

SECTION 5, 510(k) Summary

smiths

510(K) SUMMARY:

Smiths Medical ASD, Inc.

Anesthesia and Safety Devices Division

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AUG 01 2006

Company Information:

Smiths Medical ASD, Inc.
160 Weymouth Street
Rockland, MA 02370
(603) 352-3812, prompt 4, ext 2457
Contact: Timothy J. Talcott
Director, Regulatory Affairs and Compliance

Summary Prepared: May 26, 2006

Product Name:

Trade Name: Level 1® Snuggle Warm® Pediatric Underbody Blanket
Common Name: Convective Warming System

Classification Name: Thermal Regulating System (21 CFR 870.5900, Product Code DWJ)

Predicate Device(s):

K011907 Smiths Medical ASD, Inc. (formerly Level 1 Inc.), Snuggle Warm® 4000 Convective Warming System. The Snuggle Warm® 4000 Convective Warming System consists of a Convective Warming Unit, a hose (that connects to the Convective Warming Unit on one end) and a blanket; which connects onto the other end of the hose. The forced warm air travels from the Warming Unit through the hose to the blanket that is placed on the patient. There are currently 7 variations of Convective Warming Blankets in the non-sterile blanket family.

Disposables Single-Use Blankets

- SW2001 Full Body Blanket
- SW2002 Pediatric Blanket
- SW2003 Upper Body Blanket
- SW2004 Lower Body Blanket
- SW2005 Neonate to Small Child Intraoperative Blanket
- SW2006 Preemie to Neonate Intraoperative Blanket
- SW2007 Tube Blanket

Device Description:

Snuggle Warm® 4000 Convective Warming System that will include the Pediatric and Large Pediatric Underbody blankets (Model SW2009 & SW2011)

- The Snuggle Warm® 4000 Convective Warming System, identified as a Thermal Regulation System by the FDA, consists of a Convective Warming Unit (temperature controller), a hose, and a single-use Convective Warming Blanket (including the underbody blankets).
- The Snuggle Warm® 4000 Convective Warming System's single-use disposable Convective Warming Blankets (including the underbody blankets) are placed in contact with the patient and attached to a warming unit via a hose with end temperature controls. The warming unit generates warm air that is distributed throughout the warming blanket to warm the patient during and after surgical procedures.
- It is intended for thermal regulating a patient's temperature to prevent hypothermia by a warm air heated blanket system to reduce cold discomfort during and after surgical procedures.

The Pediatric and Large Pediatric Underbody Blankets are single-use Convective Warming Blankets that will be added to the existing Convective Warming Blanket family. The Pediatric and Large Pediatric Underbody Blankets are components of the Snuggle Warm® 4000 Convective Warming System of which the indications for use remains the same.

Indications for Use:

For thermal regulation of a patient's temperature to prevent hypothermia and/or reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Technological Characteristics:

The proposed and predicate devices are made of similar materials and employ similar manufacturing processes. These blankets are intended to be used under the body, rather than over the body.

Non-Clinical Data:

Bench testing is performed to demonstrate that the proposed convective warming blankets are substantially equivalent to the existing convective warming blankets currently marketed by Smiths Medical. The blankets are designed to meet the requirements of the following standards:

- ASTM F2196:2002, Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management
- ISO 10993-1 2003, Biological Evaluation of Medical Devices – Evaluation and Testing

Clinical Data:

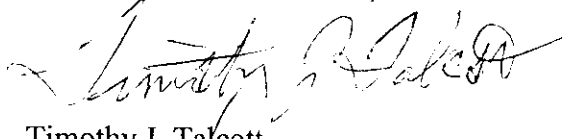
Not required

Conclusion:

The proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

SMITHS MEDICAL ASD, INC.

A handwritten signature in black ink, appearing to read "Timothy J. Talcott", is written over the printed name.

Timothy J. Talcott
Director, Regulatory Affairs and Compliance



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 01 2006

Smiths Medical ASD, Inc.
c/o Mr. Timothy J. Talcott
Director, Regulatory Affairs and Compliance
10 Bowman Drive
Keene, NH 03431-0724

Re: K061513

Level 1® Snuggle Warm® Pediatric Underbody Blanket
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulation System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: May 26, 2006
Received: June 1, 2006

Dear Mr. Talcott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

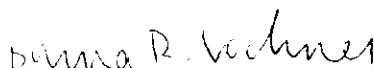
Page 2 - Mr. Timothy J. Talcott

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): K061513

Device Name: **Level 1® Snuggle Warm® Pediatric Underbody Blanket**

Indications for Use:

For thermal regulation of a patient's temperature to prevent hypothermia and/or reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan R. Kachner
(Division Sign-Off)
Division of Cardiovascular Devices

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